

Remarks

Upon entry of the foregoing amendments, claims 41-43 and 45-58 are pending in the application, with claims 41 and 58 being the independent claims.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejections.

Claim Rejection Under 35 U.S.C. § 103(a)

Claims 41-43 and 45-58 were rejected as being unpatentable over Dubensky, in view of Guan and Gregoire. Applicants respectfully traverse this rejection.

Establishing prima facie obviousness requires a showing that each claim element is taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Absent a showing of such motivation and suggestion, prima facie obviousness is not established. See *In re Fine*, 5 USPQ2d at 1598. The Federal Circuit has indicated that:

The PTO has the burden under section 103 to establish a
Prima facie case of obviousness...It can satisfy this burden
Only by showing some objective teaching in the prior art or
that knowledge generally available to one of ordinary skill in
the art would lead that individual to combine the relevant
teachings of the references. *Id.*

To meet its burden, the PTO cannot pick and choose to apply only those portions of the prior art which support the proposition that applicants claimed invention is unpatentable. This is impermissible hindsight. “One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” *Id.* at 1075, 5 USPQ2d at 1600. As the Federal Circuit has held numerous times, such a hindsight analysis is impermissible. Instead, the PTO must show suggestions, explicit or otherwise, that would compel one of ordinary skill to combine the cited references in order to make and use the claimed invention. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 f.2d 1132, 1143 (Fed. Cir. 1985).

Claims 41-43 and 45-58 are drawn to isolated expression vector, comprising (1) the sequence 5'-CACC linked immediately 5' to (2) a start codon of (3) an open reading frame (ORF), wherein the ORF is linked in-frame to (4) a polynucleotide encoding a heterologous peptide, thereby encoding a fusion protein comprising a polypeptide encoded by the ORF and the heterologous peptide.

The Office Action appears to be relying on hindsight in combining the Dubensky, Guan and Gregoire references in arriving at an obviousness determination.

The Office Action states that Dubensky discloses claim elements (1) and (2). However, the Office Action fails to appreciate that Dubensky's vectors are configured in a “bicistronic heterologous configuration” specifically designed to prevent the expression of fusion proteins. Dubensky's bicistronic vectors include a stop codon between heterologous genes, and are suitable only for the expression of single peptides

(see column 90, paragraphs 2 and 3). Dubensky's bicistronic vectors are specifically designed not to (and cannot) encode fusion proteins as required by the present claims. Ignoring this key aspect of the Dubensky disclosure and focusing only on the claim elements (1) and (2) is an inappropriate and impermissible hindsight analysis.

Moreover, the Office Action attempts to rely on the Guan and Gregoire references to provide features (3) and (4) of the claimed expression vectors. The Office Action has not provided any "*suggestions, explicit or otherwise, that would compel one of ordinary skill to combine the cited references in order to make and use the claimed invention,*" as required by the Federal Circuit. *See In re Fine* at 1598. Again, the Office Action relies on impermissible hindsight analysis to establish a *prima facie* case of obviousness. Applicants therefore respectfully request that this rejection under 35 U.S.C. § 103 be withdrawn.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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